



Implementation of a Flexible Community-Informed Toolkit for Returning Amyloid PET Results in CLARiTi

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The CLARiTi Return of Results Core

- The Consortium for Clarity in Alzheimer's Disease and Related Dementias Through Imaging (CLARiTi) project is a multi-site research initiative aiming to **harmonize neuroimaging and other biomarkers nationwide** across the 37 Alzheimer's Disease Research Centers.
- The **CLARiTi Return of Results (RoR) Core** is dedicated to aiding sites with the **return of CLARiTi Positron Emission Tomography (PET) scan results** including:
 - Developing a flexible **PET biomarker disclosure framework and toolkit**.
 - Investigating **post-disclosure outcomes**, including participant safety, feasibility, and satisfaction with learning results.

The CLARiTi RoR Toolkit

- RoR Core developed a **community-informed "Toolkit"** for returning individual amyloid (A β) PET research results to participants

Educational Resources

- For research teams** - training manual (Fig. 1), training videos, case vignettes
- For participants** - Brain Health Informational Resources & Supports, *Brain Amyloid Imaging - Learning My Results* Educational Brochure and Decision Aid (Fig. 2)

Standardized Materials

- A β PET Result Summary Report (Fig.3)
- Pre- and Post-RoR Psychological Screening Measures
 - Generalized Anxiety Disorder-7 Item (GAD-7)
 - Patient Health Questionnaire-4 Item and -9 Item (PHQ-4; PHQ-9)
 - Geriatric Depression Scale-15 Item (GDS-15)
 - Impact of Neuroimaging in Alzheimer's Disease (INI-AD)

Flexible Protocol for A β PET RoR

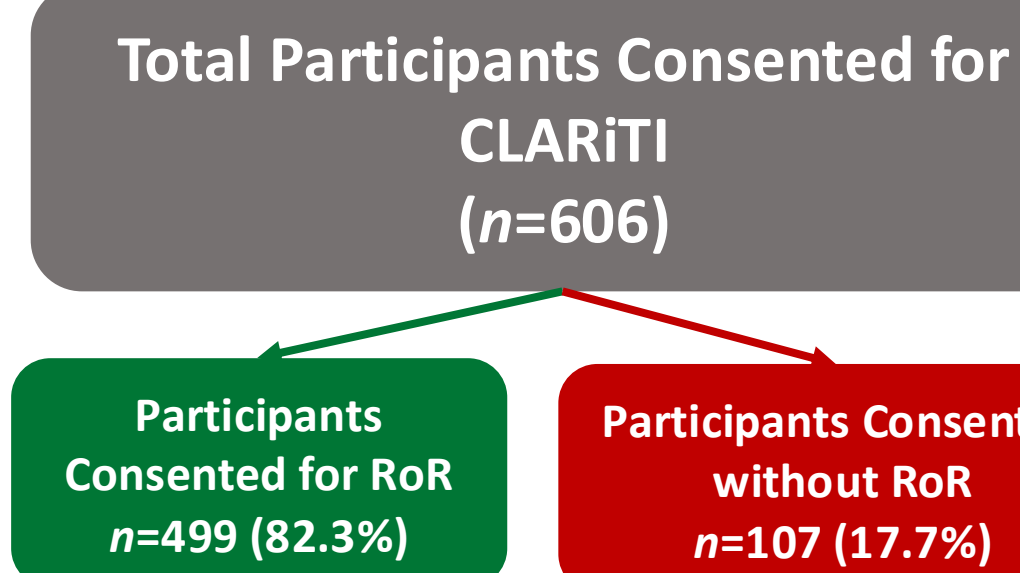
Toolkit Materials used during Completed RoR Visits (n=73)

- Pre- and Post-RoR Psychological Screening Measures (n=25)
- A β PET Educational Brochure (n=43)
- A β PET Result Summary Report (n=65)
- RoR Visit Semi-Structured Interview (n=20)
- Brain Health Informational Resources & Supports (n=33)

The CLARiTi RoR Protocol: Implementation Metrics (April 2026)

CLARiTi Consent (n=606)

- CLARiTi sites determine which participants will be offered A β PET results and select the appropriate consent form (with or without the RoR addendum).
- All participants are provided with the *Brain Amyloid Imaging - Learning My Results* Educational Brochure.



- 262 (43.4%)** participants cited **receiving results from brain scans, such as amyloid imaging, as a reason for participating**.

Pre-RoR Decision & Screening (n=159)

- Participants are asked whether they wish to receive results, and why/why not.

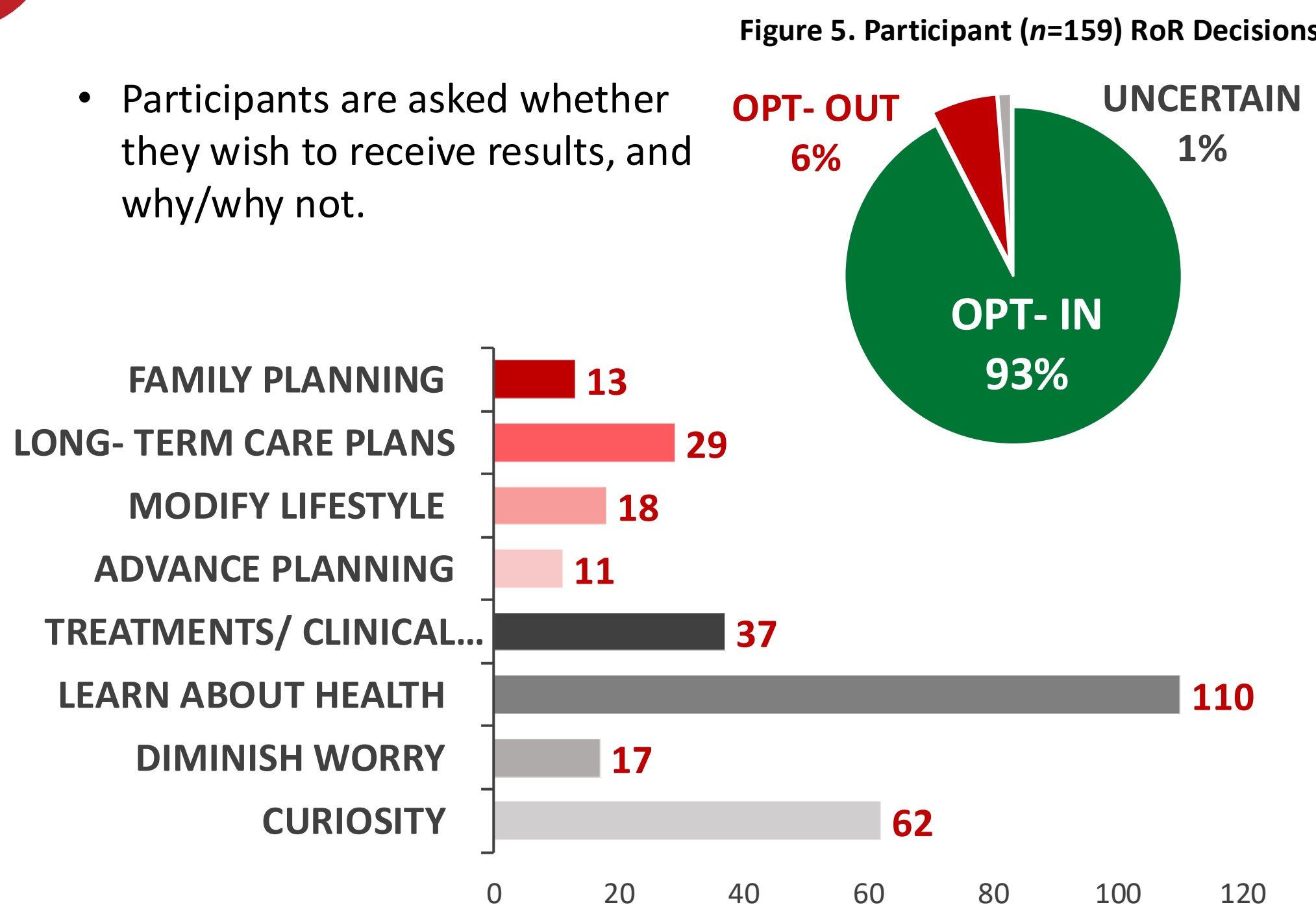
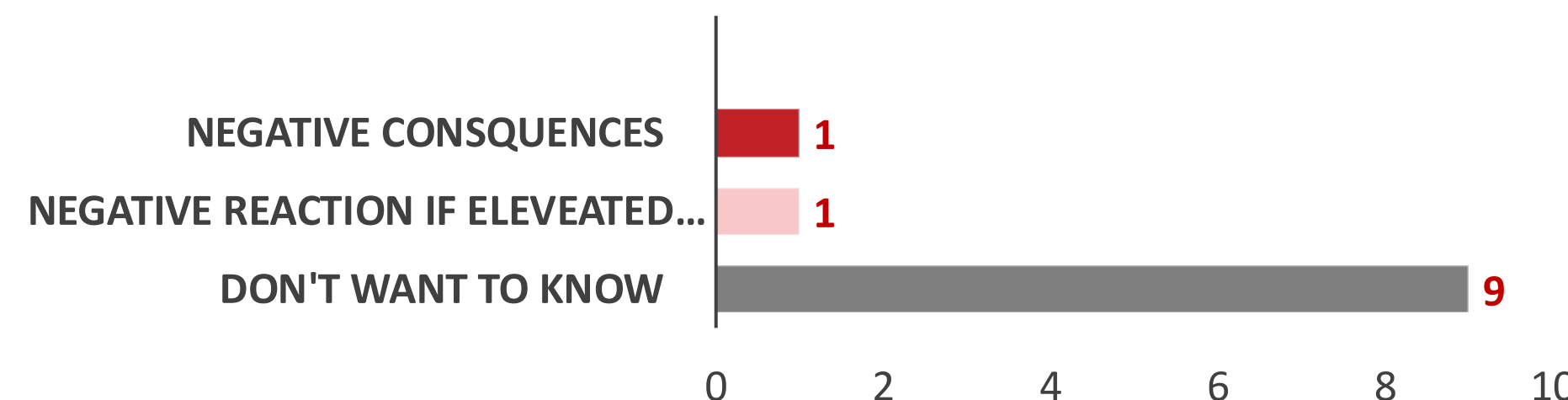


Figure 6. Reasons for Opting In to Learn A β PET Results (n=148; 'Select all that apply')



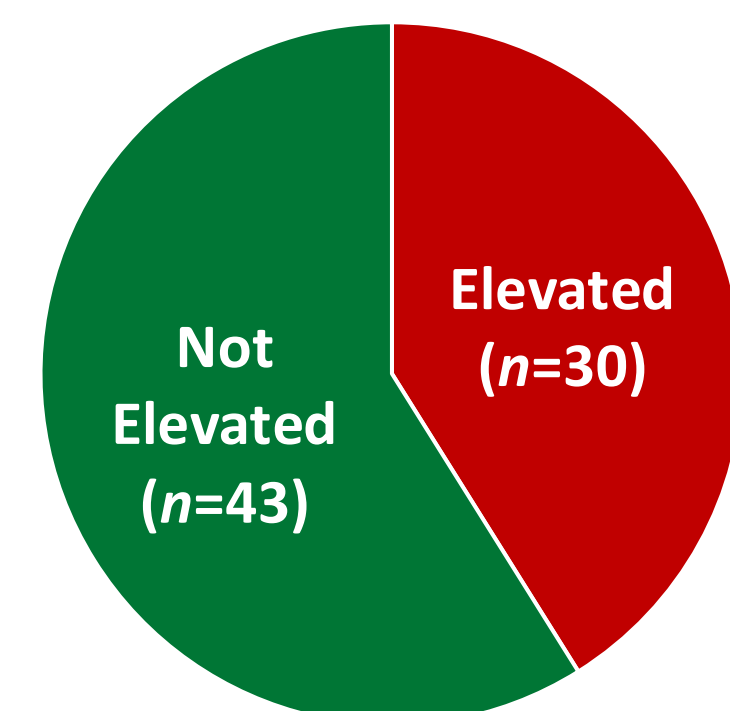
- Sites administer optional pre-RoR psychological screening measures:
 - Participants endorsed **low baseline levels of depression and anxiety**.

Table 1: Psychological Screening Scores Pre-RoR

Measure (Range; Clinical Threshold*)	PHQ-9 (0-27; $\geq 10^*$) n=34	GAD-7 (0-21; $\geq 10^*$) n=41	PHQ-4 (0-12; $\geq 6^*$) n=35	GDS-15 (0-15; $\geq 9^*$) n=42
M(SD)	3.42 (4.66)	2.24 (3.43)	0.89 (1.39)	1.44 (1.27)

A β PET RoR Visit (n=73)

- To date, **n=73 participants have received A β PET results**.
 - Mean age = 70.48 ($\pm$ 7.82)
 - Mean education = 16.86 ($\pm$ 2.90)
 - 47% Female
 - 19% from under-represented population
- Average A β PET RoR visit duration was **38 ($\pm$ 23) minutes**.
- Most RoR sessions are completed **in-person (43%) or via televideo (43%)** versus by phone (14%).
- A β PET results are disclosed as **binary reads** (elevated vs. not elevated).



Post-RoR Safety Assessment

- Sites administer optional post-RoR psychological screening measures:
 - Participants endorsed **low post-disclosure levels of depression, anxiety, or distress, irrespective of A β result disclosed (all p>.05)**.

Table 2: Psychological Screening Scores Post-RoR

Measure (Range; Clinical Threshold*)	PHQ-9 (0-27; $\geq 10^*$) n=13	GAD-7 (0-21; $\geq 10^*$) n=13	PHQ-4 (0-12; $\geq 6^*$) n=11	INI-AD Distress (0-60) n=17
M(SD)	3.85 (6.31)	3.23 (4.62)	1.82 (1.78)	4.94 (4.97)

Post-RoR Satisfaction Evaluation

Of the 16 participants who completed the satisfaction questionnaire...

- 87.5% (n=14)** agreed or strongly agreed that:
 - I was **more willing to complete a PET scan** because of the opportunity to learn results.
 - Learning my A β PET result was **useful** to me.
 - The educational and result materials were **clear and understandable**.
- 94.0% (n=15)** agreed or strongly agreed that:
 - I **understood the meaning** of my A β PET result.
 - I had **enough information to make the decision** to learn my PET result.

Conclusion & Future Directions

- Participants strongly desire their A β PET results; in fact, the opportunity to learn results may motivate study enrollment.
- Preliminary data align with other studies demonstrating the psychological safety of learning research results.
- CLARiTi Sites are actively utilizing the RoR Toolkit to guide procedures.

Future Directions:

- The CLARiTi RoR Core will launch an integrated Tau PET RoR protocol with associated training in Y4.
- Continued data collection across the ADRC network will allow deeper understanding of the feasibility, efficacy, and safety of returning individual biomarker results.

Acknowledgements: This work was supported through funding from the National Institute on Aging (U01AG082350; PIs: Johnson/Mormino).

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